DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 1, 2014

CHEMTRON BIOTECH, INC.
JANE ZHANG
QA/RA DIRECTOR
9245 BROWN DEER ROAD, SUITE B
SAN DIEGO CA 92121

Re: K142580
Trade/Device Name: Chemtrue® Multi Panel DOA Dip Card Tests
Chemtrue® Multi Panel DOA Dip Card with OPI 2000 Tests
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: II
Product Code: DKZ, LCM, DIO, LDJ, LAF, DJG, DIS, JXM, DJC, DJR, DNK
Dated: November 3, 2014
Received: November 4, 2014

Dear Ms. Jane Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142580

Device Name
Chemtrue® Multi-Panel DOA Dip Card Tests
Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests

Indications for Use *(Describe)*

Chemtrue® Multi-Panel DOA Dip Card Tests:
The Chemtrue® Multi-Panel DOA Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Cocaine, Marijuana, Morphine, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone and Oxycodone drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel DOA Dip Card Tests panel can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates and Oxycodone. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests:
The Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Cocaine, Marijuana, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines. Barbiturates, Ecstasy, Methadone and Oxycodone drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Opiates	OPI	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25

Marijuana	THC	11-nor-Δ9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates and Oxycodone. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

AS REQUIRED BY 21 CFR 807.92(c)

A. SUBMITTER: Chemtron Biotech, Inc. 9245 Brown Deer Road, Suite B, San Diego, CA 92121.
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Date Prepared: November 20, 2014

B. DEVICE

Trade or Proprietary Name: Chemtrue® Multi-Panel DOA Dip Card Tests
Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests

Common Name: Multi-Drug Urine Test Panel

Regulatory Class: Class II

This 510(k) has been submitted for clearance of new drugs of abuse dip card devices that combines drugs of abuse test strips from previously FDA cleared Chemtrue Single/Multi-Panel Drug Screen Dip Card/Cassette Tests (k102203, k111322, k121339, and k123080). These tests have been previously cleared for prescription use (k102203 and k111322) and over-the-counter use (k121339 and k123080) for the following drugs of abuse analytes in the table below. The new devices are intended for over-the-counter and prescription use:

Drug of Abuse	Product Code	Panel	Regulation Section
Amphetamine	DKZ	Toxicology 91	21CFR 862.3100, Amphetamine Test System
Cocaine	DIO	Toxicology 91	21 CFR 862.3250, Cocaine and metabolites Test System
Methamphetamine	LAF	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Opiates	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Phencyclidine	LCM	Toxicology 91	Unclassified, Enzyme immunoassay Phencyclidine
Marijuana	LDJ	Toxicology 91	21 CFR 862.3870, Cannabinoids Test System
Benzodiazepines	JXM	Toxicology 91	21 CFR 862.3170, Benzodiazepines Test System
Barbiturates	DIS	Toxicology 91	21 CFR 862.3150, Barbiturates Test System
Ecstasy (MDMA)	DJC	Toxicology 91	21 CFR 862.3610, Methamphetamine Test System
Methadone	DJR	Toxicology 91	21 CFR 862.3620, Methadone Test System
Oxycodone	DJG	Toxicology 91	21 CFR 862.3650, Opiate Test System
Morphine	DNK	Toxicology 91	21 CFR 862.3640, Morphine Test System

C. PREDICATE DEVICES

510(k): k102203, k111322, k121339 and k123080. Chemtrue Single/Multi-Panel Drug Screen Dip Card/Cassette Tests

D. INDICATIONS FOR USE:

Device Name: Chemtrue® Multi-Panel DOA Dip Card Tests

Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests

Chemtrue® Multi-Panel DOA Dip Card Tests:

The Chemtrue® Multi-Panel DOA Dip Card Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Cocaine, Marijuana, Morphine, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone and Oxycodone drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	**Abbreviation**	**Calibrator**	**Cutoff Concentration** (ng/mL)
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Methamphetamine	MAMP /MET	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
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Marijuana	THC	11-nor-Δ^9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel DOA Dip Card Tests panel can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates and Oxycodone. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests:

The Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests are rapid lateral flow immunoassays for the qualitative detection of Amphetamine, Cocaine, Marijuana, Opiates

2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone and Oxycodone drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylecgonine	300
Methamphetamine	MAMP /MET	d-Methamphetamine	1000
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Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor-Δ^9-THC9-COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxymethamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Multi-Panel DOA Dip Card with OPI 2000 Tests can consist of any combination of the above listed drug analytes. The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates and Oxycodone. There are no uniformly recognized cut-off concentration levels for these drugs in urine.

E. DEVICE DESCRIPTION

The Chemtrue® DOA Tests are colloidal gold based lateral flow immunoassays for the rapid, qualitative detection of drugs of abuse in human urine. The tests are single-use, in vitro diagnostic devices, which come in the formats of dip card, cup, or cassette, as indicated by the test name.

F. SUBSTANTIAL EQUIVALENCE INFORMATION

Comparison with the predicate devices is outlined below:

Item	Candidate Devices	Predicates
Indication(s) for use	For qualitative detection of drugs of abuse in human urine	Same
Specimen Type	Human urine	Same

Methodology /Technological Characteristics	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody immunochemistry.	Same
Results	Qualitative	Same
Cut Off	Amphetamine 1000 ng/mL Cocaine 300 ng/mL Methamphetamine 1000 ng/mL Morphine 300 ng/mL Opiates 2000 ng/mL PCP 25 ng/mL THC 50 ng/mL Benzodiazepines 300 ng/mL Barbiturates 300 ng/mL Ecstasy (MDMA) 500 ng/mL Methadone 300 ng/mL Oxycodone 100 ng/mL	Same
Configurations	Dip Card	Same
Intended Use	Prescription and OTC Use	Same

G. TEST PRINCIPLE

The Chemtrue® DOA Tests are rapid lateral flow immunoassays in which chemically modified drugs (drug-protein conjugates) compete with drugs that may be present in urine. On each test strip, a drug-protein conjugate is striped on the test band of the membrane - known as the test region (T) and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug-protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result.

A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

Monoclonal anti-drug antibodies are used on the AMP/COC/MET/MOR/OPI/ PCP/THC/ BAR/MDMA/MTD/OXY Test devices which are derived from mouse. The polyclonal anti-drug antibodies are used on BZO Test devices which are derived from sheep/mouse.

H. PERFORMANCE CHARACTERISTICS

All the drugs of abuse analytes of the candidate devices (AMP, COC, MAMP, OPI, MOR, PCP, THC, BZO, BAR, MDMA, MTD, and OXY) were previously cleared under k102203, k111322, k121339, and k123080. Test strips, sample matrix, test format, and cut-off concentrations for these drugs of abuse analytes are identical to those cleared under k102203, k111322, k121339, and k123080. See k102203, k111322, k121339, and k123080 for additional precision, specificity, interference, method comparison, stability and lay-user study information.

Verification and validation activities were conducted to support combining the test strips to create the multi-panel candidate devices, including interference studies and usability testing.

I. CONCLUSION:

Based on the test principle and performance characteristics of the candidate device, it is concluded that the candidate devices are substantially equivalent to the predicate device.